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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,237

04/08/2004

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EXAMINER

GOFF II, JOHN L

ART UNIT

PAPER NUMBER

1791

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,237	Applicant(s) KELLEY, GREGORY S.	
	Examiner John L. Goff	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,11,12,16,21,24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-10,13-15,17-20,22,23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to the amendment filed on 9/4/08.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 7-10, and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
5. Claim 1 as amended requires “wherein the top cutting portion includes a top surface” and “wherein a portion of the top surface is submerged within the strip”. Applicant refers to Figures 3 and 4 for support. Figures 3 and 4 depict cutting surface 48 with a top surface. However, the top surface is not submerged within the strip. There is no description that the two sloping sides of the cutting member are cutting portions at their top surfaces. Figure 2 depicts the two sloping sides as non-cutting portions.

Claim Rejections - 35 USC § 103

6. Claims 1, 2, 4, 7-9, 13, 15, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al. (JP 05293176) in view of Larmour (U.S. Patent 2,237,152) or Most (U.S. Patent 2,127,043).

Vigil discloses a method for manufacturing a cutting balloon catheter comprising providing a strip of polymeric material (32 of Figure 2(A)), providing a cutting member/blade the cutting member/blade including a top cutting portion/surface (30 and 31 of Figure 2(B)), a top surface (33a and 33b of Figure 2(B))), and a slotted base portion having a plurality of slots, embedding the cutting member into the strip wherein the slots of the cutting member interlock the strip with the cutting member, and attaching the strip to an angioplasty balloon (12 of Figure 1) (Paragraphs 0016 and 0017). Vigil does not specifically teach how the cutting member, a metal blade, is embedded in the strip, a polyurethane strip. It is extremely well known in the art to inexpensively embed a metal member within a strip of polymeric material by heating the strip to melt and liquefy at least a portion of the strip, disposing the metal member adjacent the strip, submerging at least a portion of the metal member in the liquefied portion, and cooling to solidify the strip and interlock the metal member and strip as shown by Larmour (Figures 1 and 2 and Page 1, Column 1, lines 32-35 and 44-49 and Page 2, Column 1, lines 3-5 and 21-25) or Most (Page 1, Column 2, lines 26-32 and 49-52 and Page 2, Column 2, lines 24-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to embed the cutting member within the strip of polymeric material as taught by Vigil using a well known inexpensive method including heating the strip to melt and liquefy at least a portion of the strip as shown by Larmour or Most.

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As to the limitation of “so that a portion of the top surface is submerged within the joining member”, Figure 2(A) of Vigil does not depict the top surface (33a and 33b of Figure 2(b)) of the cutting member/blade such that the top surface is considered submerged within the joining member. As to the limitations of “wherein the top cutting portion includes a top surface” and “wherein a portion of the top surface is submerged within the strip”, Vigil teaches a top cutting portion and top surfaces (30 and 31 of Figure 2(B)). It would have been obvious to one of ordinary skill in the art at the time the invention was made that embedding the cutting member/blade as taught by Vigil as modified by Larmour or Most would have included embedding the top surfaces (30, 33a, and 33b) to some extent to firmly interlock the strip with the cutting member/blade as Figure 2(A) of Vigil does not depict at least a portion of the top surfaces (33a and 33b) and the extent embedding is not critical as shown by Figure 3 of Vigil other than the top surface used for cutting (31 of Figure 2(B)) is not embedded.

7. Claims 1, 2, 4, 7-9, 13-15, 17, 18, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most as applied to claims 1, 2, 4, 7-9, 13, 15, 17, 18, and 20 above, and further in view of Radisch (U.S. Patent 2003/0040770).

Regarding claims 1, 2, 4, 7-9, 13, 15, 17, 18, and 20, as noted above Vigil is considered to teach a top cutting portion and top surfaces (30 and 31 of Figure 2(B)). In the event it is shown the side surface with a top surface (30 of Figure 2(B)) is not a top cutting portion the following rejection would apply. It was known in the art that the top surfaces of the side surface of the cutting member/blade include cutting portions as shown by Radisch (28a of Figure 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the cutting member/blade taught by Vigil as modified by Larmour or Most side

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surfaces with top surfaces including cutting portions as shown by Radisch such that the side surfaces are capable of cutting.

Regarding claims 14 and 25, Vigil and Larmour or Most as applied above teach all of the limitations in claims 14 and 25 except for a specific teaching of disposing a second cutting blade adjacent strip. It was known in the art to include more than one cutting blade adjacent the strip to form an effective cutting edge that conforms to the surface being cut as shown by Radisch (Paragraph 0028). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include adjacent the strip taught by Vigil at least a second cutting blade to form an effective cutting edge that conforms to the surface being cut as shown by Radisch.

8. Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most (or Vigil and Larmour or Most and Radisch) as applied to claims 1, 2, 4, 7-9, 13, 15, 17, 18, and 20 above, and further in view of Lim et al. (U.S. Patent 7,147,619).

Vigil and Larmour or Most (or Vigil and Larmour or Most and Radisch) as applied above teach all of the limitations in claims 3 and 19 except for a specific teaching of heating to melt the strip of polyurethane using a laser. Vigil as modified by Larmour or Most (or Vigil as modified by Larmour or Most and Radisch) is generally directed to heating the strip of polyurethane to melt the strip wherein the specific means for application of heat is not critical or limited. It was known in the art that it was suitable to heat polyurethane portions of a catheter to its melting temperature using a laser as shown by Lim (Column 9, lines 1-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the strip of polyurethane taught by Vigil as modified by Larmour or Most (or Vigil as modified by Larmour

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or Most and Radisch) to melt the strip using any known suitable means such as laser as shown by Lim only the expected results being achieved.

9. Claims 10, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil and Larmour or Most (or Vigil and Larmour or Most and Radisch) as applied to claims 1, 2, 4, 7-9, 13, 15, 17, 18, and 20 above, and further in view of Forman et al. (U.S. Patent 5,514,092).

Vigil and Larmour or Most (or Vigil and Larmour or Most and Radisch) as applied above teach all of the limitations in claims 10, 22, and 23 except for a specific teaching of attaching the strip to the balloon by heating. Vigil suggests as exemplary attaching by adhesive, but Vigil is not limited to any particular attaching means. It was known in the art that it was suitable to attach the balloon of the catheter to other members using any of heat with laser, adhesive, etc. as shown by Forman (Column 9, lines 5-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the strip to the balloon as taught by Vigil as modified by Larmour or Most (or Vigil as modified by Larmour or Most and Radisch) using any of laser welding, adhesives, etc. as was known as suitable as shown by Forman wherein laser welding has the obvious advantage of not requiring an adhesive.

Response to Arguments

10. Applicant's arguments with respect to claims 1-4, 7-10, 13-15, 17-20, 22, 23, and 25 have been considered but are moot in view of the new ground(s) of rejection.

The claims as amended are fully addressed above.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **John L. Goff** whose telephone number is **(571)272-1216**. The examiner can normally be reached on M-F (7:15 AM - 3:45 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John L. Goff/
Primary Examiner, Art Unit 1791